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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,330	03/07/2007	Thomas A. Osborne	8627/1247 (PA-5573-PCT/US)	3188
48004 7590 10/01/2009 BRINKS HOFER GILSON & LIONE/INDY/COOK BRINKS HOFER GILSON & LIONE CAPITAL CENTER, SUITE 1100 201 NORTH ILLINOIS STREET INDIANAPOLIS, IN 46204-4220			EXAMINER PIERY, MICHAEL T	
			ART UNIT 1791	PAPER NUMBER
			MAIL DATE 10/01/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/581,330	<b>Applicant(s)</b> OSBORNE, THOMAS A.	
	<b>Examiner</b> MICHAEL T. PIERY	<b>Art Unit</b> 1791	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 May 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-10 and 21-30 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 21-30 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 01 June 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
  2. Ascertaining the differences between the prior art and the claims at issue.
  3. Resolving the level of ordinary skill in the pertinent art.
  4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
2. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over applicant's admitted prior art (specification pages 1-3) in view of van Muiden (EP 0662385).

Regarding claim 1, AAPA teaches positioning a sleeve over a mandrel and heating the mandrel (paragraph 0006). AAPA does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches positioning a first polymeric sleeve with a striped helical pattern over a mandrel and positioning a second polymeric sleeve with a striped helical pattern over the first sleeve to define a braid-like configuration (column 4, lines 25-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of AAPA with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of AAPA (paragraph 0007).

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Regarding claim 2, AAPA does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the sleeves have a striped helical pattern (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of AAPA with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of AAPA (paragraph 0007).

Regarding claims 3-5, AAPA does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the stripes extend from the outer surface to the inner surface of both sleeves (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of AAPA with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of AAPA (paragraph 0007).

Regarding claim 6, AAPA does not explicitly teach sleeves are coextruded with stripes. However, van Muiden teaches the sleeves are co-extruded with the stripes (column 2, lines 43-47). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of AAPA with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of AAPA (paragraph 0007).

Regarding claims 7-9, AAPA teaches it is known to place an inner liner material over a mandrel then place a coil over the inner liner then bond a sleeve to the coil and heating the layers in a shrink tube (paragraph 0006). AAPA does not explicitly teach multiple sleeves with helical

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stripes. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of AAPA with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of AAPA (paragraph 0007).

Regarding claim 10, AAPA does not explicitly teach a sleeve comprises two segments. However, van Muiden teaches forming a sleeve with two sleeve segments, specifically one with high pitch and one with low pitch (column 3, lines 30-41). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify AAPA to include multiple segments because the multiple segments allow for variation in properties, such as stiffness, along the length of the catheter.

3. Claims 21-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Parker (US 5,380,304) in view of van Muiden (EP 0662385).

Regarding claim 21, Parker teaches positioning an inner liner over a mandrel, positioning a coil over the inner liner, positioning a polymeric sleeve over the coil, positioning a heat shrink material over the sleeve, heating the assembly to cause the heat shrink material to shrink further causing the sleeve to melt and bond to the inner liner through the coil turns (figure 3). Parker does not explicitly teach two polymeric sleeves. However, van Muiden teaches a two layer polymer sleeve for a catheter including a first polymeric sleeve with a striped helical pattern and a second polymeric sleeve with a striped helical pattern with a pitch opposite the first striped extrusion to define a braid-like configuration (column 4, lines 25-44). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of

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Parker with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker (column 1, lines 19-38).

Regarding claim 22, Parker teaches removing the mandrel and heat shrinking sleeve (column 5, lines 39-41).

Regarding claim 23, Parker does not explicitly teach multiple sleeves with helical stripes. However, van Muiden teaches the stripes extend from the outer surface to the inner surface of both sleeves (figure 4). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Parker with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker.

Regarding claim 24, Parker does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches two sleeves with helical patterns. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Parker with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker.

Regarding claim 25, Parker does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches the sleeves are coextruded with the striped extrusion (column 4, lines 25-38). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Parker with the two helical striped sleeves of van Muiden

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because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker.

Regarding claims 26 and 27, Parker does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches it is known to vary the composition and pattern of extrudates in order to vary the stiffness and physical properties of the sheath. It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Parker with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker.

Regarding claim 28, Parker teaches the sleeve is formed by polyamide material (column 2, line 36).

Regarding claim 29, Parker does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches it is known to form sleeves of polyamide material with a higher durometer stripe (column 5, lines 10-15). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Parker with the two helical striped sleeves of van Muiden because the configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker.

Regarding claim 30, Parker does not explicitly teach multiple sleeves with helical stripes; however, van Muiden teaches forming the sleeves by a stripe extrusion process (column 4, lines 1-20). It would have been obvious to one of ordinary skill in the art at the time of the invention to substitute the sleeve of Parker with the two helical striped sleeves of van Muiden because the

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configuration taught by van Muiden provides good compression resistance and reliable torsion stiffness (column 1, lines 28-30) desired properties of Parker.

### ***Response to Arguments***

Applicant's arguments filed May 22, 2009 have been fully considered but they are not persuasive.

Applicant argues that van Muiden teaches two layers and, therefore, teaches away from a sheath having a small wall thickness. The examiner disagrees. Rather, van Muiden teaches that the sheath provides the desired combination of properties including thickness, torsional stiffness and pressure resistance. Further, van Muiden teaches the dual sleeve sheath is an improvement over the typical tube-like basic body (column 1, lines 5-12).

### ***Conclusion***

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.



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Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL T. PIERY whose telephone number is (571)270-5047. The examiner can normally be reached on M-Th 8:30-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Johnson can be reached on (571) 272-1176. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael T Pery/  
Examiner, Art Unit 1791

/Monica A Huson/  
Primary Examiner, Art Unit 1791